Arecor Therapeutics

AT278 Phase I delivers better than expected results

20 September 2021

- The Phase I trial of Arecor's ultra-concentrated ultra-rapid insulin, AT278, has met all primary and secondary endpoints, demonstrating a superior pharmacokinetic (PK) and pharmacodynamic (PD) profile to a comparable dose of lower concentration of NovoRapid (NovoNordisk's gold standard rapid acting insulin).
- The trial evaluated 38 adults with Type I diabetes in an euglycaemic clamp setting comparing AT278 with NovoRapid, with the aim of establishing PK/PD equivalence. A subcutaneous dose of AT278 0.3 U/Kg (500 U/mL) was compared with 0.3 U/Kg NovoRapid (100 U/mL). AT278 matched or exceeded key measures such as glucose lowering, onset of action, and absorption profile, and there were no safety signals.
- The results are impressive as AT278 is an ultra-concentrated rapid acting insulin, which is five-fold (500 U/ml) more concentrated than the NovoRapid comparator. The formulation of a higher concentration rapid-acting insulin is challenging as increases in concentration typically result in notably reduced absorption, slowing the onset of action and shifting the absorption curves of concentrated formulations to the right.
- Such challenges mean there are no high concentration rapid mealtime (prandial) insulins available, with the highest concentration rapid product being Humalog U-200 (lispro, Eli Lilly) at 200 U/ml. The existing 500 U/ml products, such as (Humulin U-500), are slower acting. Thus, these Phase I results position ART278 as a disruptive formulation, opening up the prandial insulin market as the only concentrated rapid-acting insulin.
- In addition, there are a growing number of patients with high daily insulin requirements (>200 units/day), typically Type II and refractory Type I diabetics. AT278's appeal is not simply to reduce the injection burden, but to allow wider access to next-generation miniaturised insulin pumps (where their smaller size often results in limited reservoir capacities). Importantly, algorithm-driven devices require a rapid acting insulin to optimise glycaemic control.

Price	247p
Market Cap	£68.4m
Primary exchange	AIM
Sector	Healthcare
Company Code	AREC
Corporate client	Yes

Company description:

Arecor Therapeutics is a revenue-generating clinical stage drug developer, with a well-balanced portfolio of in-house and partnered programmes. Its proprietary Arestat formulation platforms result in enhanced products with lower development risks and less onerous regulatory approvals.

Trinity Delta view: AT278's Phase I results have demonstrated a better-than-expected absorption profile that positions it as a unique and highly desirable rapid acting ultra-concentrated insulin. Its profile could address unmet needs in both the prandial and high insulin requiring diabetes markets, as well as potentially lowering the barrier to adoption of insulin pumps. Planning is underway to initiate the next clinical study in 2022 to further demonstrate the benefits of AT278. We expect licencing discussions to follow a Phase II study and data package completion (clinical, stability and toxicology). The AT278 results also highlight the strength of Arecor's formulation expertise, confirming its ability to develop novel products with enhanced properties, improved physical characteristics, and better therapeutic profiles. We recently initiated coverage (September 2021 Initiation) with a £103.7m (374p per share) valuation.

Analysts

Lala Gregorek

lgregorek@trinitydelta.org

+44 (0) 20 3637 5043

Franc Gregori

fgregori@trinitydelta.org

+44 (0) 20 3637 5041

Lala Gregorek lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Disclaimer

More information is available on our website: www.trinitydelta.org